

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA PRODUCTS L.P., NAPP)	
PHARMACEUTICAL GROUP LTD., BIOVAIL)	
LABORATORIES INTERNATIONAL SRL, and)	
ORTHO-MCNEIL, INC.,)	
)	C.A. No. 07-255-JJF
Plaintiffs,)	
)	
v.)	
)	
PAR PHARMACEUTICAL, INC. and PAR)	REDACTED
PHARMACEUTICAL COMPANIES, INC.,)	PUBLIC VERSION
)	
Defendants.)	

**DEFENDANTS' REPLY BRIEF IN SUPPORT OF MOTION TO COMPEL
PRODUCTION OF CERTAIN DISCOVERY AND AMEND SCHEDULING ORDER**

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TABLE OF CONTENTS

INTRODUCTION	1
A. Fact Discovery	1
B. Documents Relating to Testing Based on the Merck Reference	2
C. The “Inadvertently” Produced Documents	3
ARGUMENT	4
A. The Court Has Not Denied Any Part of Par’s Motion Concerning the Discovery Schedule	4
B. Plaintiffs Have Still Not Complied With Their Discovery Obligations Concerning the Experimental Testing Performed Using the Merck Reference as a Guideline	6
1. Plaintiffs’ Production of Sixteen Documents with Their Opposition Brief Does Not Moot this Issue	6
2. Plaintiffs’ Withholding of Documents Concerning the Experimental Testing Performed Using the Merck Reference Continues to Prejudice Par	7
C. The 65,000 Pages Withdrawn By Plaintiffs On at Least Sixteen Separate Occasions Were Not “Inadvertently” Produced	9
1. Plaintiffs’ Reliance on <i>Berg Electronics v. Molex</i> for the Strict/Intent Standard Supports Par’s Position	9
2. Under the Balancing Test, the 65,000 Pages of Recalled Documents Should Be Produced	10
a. Precautions Taken By Purdue and Napp	10
b. The Number of Inadvertent Disclosure	11
c. The Extent of the Disclosure	11
d. Delay In Rectifying the Inadvertent Disclosures	12
e. Fairness	14
CONCLUSION	14

TABLE OF AUTHORITIES

Cases

<i>Advanced Med., Inc. v. Arden Med. Sys., Inc.</i> , No. 87-3059, 1988 U.S. Dist. LEXIS 7297 (E.D. Pa. July 18, 1988).....	10
<i>Bensel v. Air Line Pilot Ass'n</i> , 248 F.R.D. 177 (D.N.J. 2008).....	10, 12
<i>Berg Elecs., Inc. v. Molex, Inc.</i> , 875 F. Supp. 261 (D. Del. 1995).....	9
<i>Bud Antle, Inc. v. Grow-Tech Inc.</i> , 131 F.R.D. 179 (N.D. Cal. 1990).....	14
<i>Ciba-Geigy Corp. v. Sandoz Ltd.</i> , 916 F. Supp. 404 (D.N.J. 1995).....	10, 12
<i>Maldonado v. New Jersey</i> , 225 F.R.D. 120 (D.N.J. 2004).....	12
<i>New Bank of New England v. Marine Midland Realty Credit Corp.</i> , 138 F.R.D. 479 (E.D. Va. 1991).....	13
<i>Sherlock v. Lockheed Martin Corp.</i> , No. 01-254, 2002 U.S. Dist. LEXIS 27753 (D. Md. Dec. 18, 2002).....	11, 12, 13

INTRODUCTION

On June 12, 2008, Par requested that the Court order the following relief:

- Extend fact discovery to allow completion of any discovery noticed before June 5; (ii) allow discovery, if any, necessitated by late document productions; and (iii) reschedule the deadline for expert reports for a date after the completion of fact discovery, or in the alternative, permit the parties to supplement and/or add expert reports.
- In view of a subject matter waiver, the Court order Purdue and Napp to produce all documents from their privilege logs relating to the experimental testing using the Merck reference as a guideline.
- The Court order that the over 65,000 pages (approximately 1000 documents) withdrawn by Purdue and Napp over the last four months were not inadvertently produced and hence any privilege claim is waived.

A. Fact Discovery

Purdue and Napp (“plaintiffs”) misinterpret the Court’s June 18th Order by claiming that the Court already denied a portion of Par’s motion. (Ex. A). On June 12th, Par requested that the Court address the deadline for the exchange of expert reports in view of the scheduled June 20th date for exchanging initial expert reports. (Ex. B). The following day, the Court instructed Par to “Please formalize your request regarding expert reports and e-file it today.” (Ex. C). Par complied. (D.I. 156). On June 18, 2002, the Court issued the following Order: “The request to extend expert reports deadline until June 20, 2008 is GRANTED. All other dates remain.” (Ex. A). The Court did not deny Par’s request. (*See* D.I. 176, Opposition Br., at 1). The Court specifically ruled that the expert reports deadline be extended, but did not deny any part of the motion. (Ex. A). Accordingly, the Court granted Par’s request for an extension to complete expert reports but has not yet ruled on Par’s request to (i) complete fact discovery that was noticed before June 5, 2008; and (ii) to allow discovery, if any, necessitated by late document productions.

B. Documents Relating to Testing Based on the Merck Reference

Despite plaintiffs' continued assertion during fact discovery that certain documents concerning the Merck reference are privileged and/or work product (*see e.g.*, Ex. D), plaintiffs now do not appear to contest that a subject matter waiver has occurred relating to the experimental testing performed using the Merck reference as a guideline. Rather, plaintiffs argue that this issue is moot and/or that they are not required to produce such documents based on an earlier Court order:

- Plaintiffs argue that the issue of subject matter waiver is moot because they produced sixteen documents concurrently with their answering brief. Plaintiffs are silent on the subject matter waiver issue. Further, plaintiffs' untimely production contains documents already produced and illustrates that Purdue is either withholding or has destroyed highly relevant documents that Par has specifically requested. (Ex. E).
- Plaintiffs misconstrue this Court's May 9, 2008 Order concerning Par's motion to compel the production of non-privileged foreign documents by alleging that "[i]n March 2008, Par moved to compel Napp to search the files of its internal law department and foreign outside counsel and to produce any documents relating to these tests. On May 9, 2008, the Court denied Par's motion. (D.I. 126)." (D.I. 176, Opposition Br., at 6). This Court's May 9, 2008 Order did not address documents withheld as privileged based on the subject matter waiver relating to the experimental testing performed using the Merck reference as a guideline. (D.I. 126).

Although plaintiffs claim they "reviewed" their privilege logs for documents relating to Merck testing conducted by Napp (D.I. 176, Opposition Br., at 7), plaintiffs do not represent that all documents concerning the experimental testing using the Merck reference as a guideline have been produced or have been destroyed. For this issue to be resolved, plaintiffs should produce the requested documents or make the clear and unequivocal representation that all documents concerning the experimental testing performed using the Merck reference as a guideline have been produced or explain why those documents no longer exist.

C. The “Inadvertently” Produced Documents

The declaration of Sona De makes clear that plaintiffs cannot state with any certainty what precautions were taken to protect the allegedly privileged documents from inadvertent production. (See D.I. 177, De Decl., ¶¶ 19-21). In particular, a substantial portion of the declaration is based on information and belief—not first-hand knowledge. The declaration also confirms that the same documents were recalled several times, i.e. “about 100 were duplicates.” (D.I. 177, De Decl., ¶ 7). The production of an allegedly privileged document multiple times supports that plaintiffs intended to produce them. More significantly, plaintiffs rely on a miscalculation to justify their “inadvertent” document productions. Of the 2.3 million pages¹ that plaintiffs and third parties produced, 65,000 pages have been recalled to date. 65,000 pages out of 2.3 million pages equals approximately 3%—not “less than 0.3%” as plaintiffs have stated in their brief. (D.I. 176, Opposition Br., at 3, 12, 19; D.I. 177, De Decl., ¶ 27). Although plaintiffs may be able to represent that 0.3% is “negligible” or a “small fraction,” they cannot make the same representation with regard to 3%. (See D.I. 176, Opposition Br., at 1, 19). Additionally, realizing privileged documents may have been produced, a prudent party would have promptly reviewed its document production once again to ensure that other privileged documents were not overlooked. Plaintiffs’ failure to once again review its documents to rectify the error of inadvertent disclosure supports the conclusion of waiver. Applying either the “strict/intent standard” or the “balancing test,” to determine if documents were inadvertently

¹ The De Declaration states that Purdue and Napp produced 2.3 million pages. (D.I. 177, De Decl., ¶ 27). Purdue and Napp, however, produced approximately 1.5 million pages. For purposes of this reply, however, Par will agree to base its calculations on plaintiffs’ 2.3 million pages figure that also includes documents produced by third parties (Mundipharma and Davidson, Davidson & Kappel).

produced, plaintiffs have waived privilege concerning the approximately 65,000 recalled pages to date.

ARGUMENT

A. The Court Has Not Denied Any Part of Par's Motion Concerning the Discovery Schedule

Plaintiffs do not address the portion of Par's motion asking the Court to allow for completion of fact discovery noticed before June 5, 2008 and for additional discovery, if necessary, based on any new document productions. Instead, plaintiffs read the Court's June 8, 2008 order to deny Par's request.

Counsel for Par emailed the Court on June 12, 2008 requesting a teleconference with the Court to address Par's request that "the present deadline for the exchange of expert reports be extended." (Ex. B). The following day the Court responded to all counsel in the case instructing Par's counsel to "Please formalize your request in writing regarding expert reports and e-file it today." (Ex. C). Par complied with the Court's instructions, and on June 17, 2008, the Court ruled: "The request to extend expert reports deadline until June 20, 2008 is GRANTED. All other dates remain." (Ex. A). Par does not read this order as a denial of its request to allow completion of fact discovery noticed before June 5 or as a denial of its request to allow discovery, if any, necessitated by late document productions.

With regard to completing discovery noticed prior to the June 5th fact discovery deadline, Par is particularly interested in taking the deposition of Adrian Brown. Par noticed Adrian Brown on May 30th-one day after Dr. Prater's May 29th deposition. Mr. Brown is a former employee of Napp, and the person who carried out the experimental work set forth in the Malkowska declarations under the supervision of Dr. Prater, as well as experimental work that was inconsistent with the Malkowska declarations submitted to the U.S. Patent Office.

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Par noticed Mr. Brown's deposition the next day—May 30th. Plaintiffs have taken the position that the notice is objectionable because it was served less than seven days before the June 5th cut-off of fact discovery. (Ex. G). Moreover, plaintiffs claim that this witness is not within plaintiffs' control. (Ex. G). Other former Napp employees, however, have been appearing based on an obligation in their employment agreements to assist the company in protecting patents. Likewise, Mr. Brown should be in Napp's control.

B. Plaintiffs Have Still Not Complied With Their Discovery Obligations Concerning the Experimental Testing Performed Using the Merck Reference as a Guideline

1. Plaintiffs' Production of Sixteen Documents with Their Opposition Brief Does Not Moot this Issue

In an attempt to moot the subject matter waiver issue, plaintiffs produced sixteen documents along with their opposition brief. These sixteen documents, some of which are duplicates of already produced documents, further highlight deficiencies in plaintiffs' production. Moreover, it is clear from discovery that there is other highly relevant information that has not been produced. Apparently, plaintiffs are unable to locate or are still withholding documents which have been specifically requested on multiple occasions. For example, plaintiffs have not produced analytical data that relates to the experimental testing performed using the Merck Reference as a guideline. (Ex. E). Such information should be stored on Napp's electronic Laboratory Information Management System ("LIMS").

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Accordingly, such information should be available for production unless it has been intentionally deleted. Plaintiffs should produce these and other highly relevant documents related to the subject matter of the experimental testing using the Merck reference as a guideline or if they no longer exist, provide details about who deleted the information from the LIMS system and when.

2. Plaintiffs' Withholding of Documents Concerning the Experimental Testing Performed Using the Merck Reference Continues to Prejudice Par

Par continues to be prejudiced by plaintiffs' withholding of documents that contradict information submitted to the U.S. Patent Office. In fact, plaintiffs have consistently and continually prevented Par from obtaining discovery, including documents and deposition testimony,)

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Because plaintiffs continue to withhold documents and prevent testimony concerning subject matter in which privilege has been waived, Par respectfully requests that the Court order plaintiffs to produce the documents relating to the experimental testing performed using the Merck reference and direct plaintiffs to allow their witnesses to answer questions pertaining to this subject matter.

C. The 65,000 Pages Withdrawn By Plaintiffs On at Least Sixteen Separate Occasions Were Not “Inadvertently” Produced

The protective order in this case only protects “inadvertently” produced documents. The 65,000 pages in this case were not “inadvertently” produced.

1. Plaintiffs’ Reliance on *Berg Electronics v. Molex* for the Strict/Intent Standard Supports Par’s Position

Plaintiffs contend that this Court follows a strict/intent standard to determine whether an inadvertent production should waive privilege. (D.I. 176, Opposition Br., at 15). Even if the strict/intent standard is followed, the documents have not been inadvertently produced. The documents produced in *Molex*, unlike the documents in this case, were not intended to be produced, i.e. they were produced by mistake after counsel identified and marked the documents to be withheld.

In this case, Molex has identified a sufficient factual basis for the court to find it inadvertently produced these documents. That is, it has shown (and Berg has not disputed) that *Molex’s counsel identified the documents to be withheld, marked those documents, and someone at counsel’s law firm nevertheless copied and produced them*. It is clear that Molex and its counsel did not intend to produce these documents; on the contrary, *they intended not to produce them, and the documents were produced by mistake*.

Berg Elecs., Inc. v. Molex, Inc., 875 F. Supp. 261, 263 (D. Del. 1995) (emphasis added).

Here, it is clear that plaintiffs intended to produce the 65,000 pages of documents that were first reviewed by approximately 50 contract attorneys and then “spot checked” by plaintiffs’ counsel. (D.I. 177, De Decl., ¶ 19, 23). Plaintiffs have not asserted that they did not intend to make the production. As such, the documents were not “inadvertently” produced under the standard set forth in *Molex*.

2. Under the Balancing Test, the 65,000 Pages of Recalled Documents Should Be Produced

If the Court applies the balancing test, as has been applied by courts in the Third Circuit, any privilege assertion for the 65,000 recalled pages has been waived. *See Bensel v. Air Line Pilot Ass’n*, 248 F.R.D. 177, 180 (D.N.J. 2008) (applying the balancing test to find waiver); *Ciba-Geigy Corp. v. Sandoz Ltd.*, 916 F. Supp. 404, 411 (D.N.J. 1995) (applying the balancing test to find waiver and stating that *Redland Soccer Club, Inc. v. Dep’t of the Army*, 55 F.3d 827, 856 (3d Cir. 1995) “implies that the Third Circuit would adopt a balancing test to determine whether an inadvertent disclosure constitutes a waiver.”); *Advanced Med., Inc. v. Arden Med. Sys., Inc.*, No. 87-3059, 1988 U.S. Dist. LEXIS 7297, at *6 (E.D. Pa. July 18, 1988) (applying the balancing test).

a. Precautions Taken By Purdue and Napp

Plaintiffs cannot state with certainty what precautions were taken to protect their allegedly privileged documents. In particular, the De declaration is based on information and belief, not first-hand knowledge. Even based on Ms. De’s declaration, plaintiffs did not take reasonable precautions based on the circumstances of this case. According to the De declaration, 70% of the 5.2 million pages were in electronic form. This means that approximately 1.5 million pages were in non-searchable paper format. Since these documents were produced on CD, plaintiffs had already scanned these documents and could have easily had these documents

prepared in text-searchable format. Electronic keyword searches for attorney names could have turned up many of the documents that plaintiffs eventually recalled. At Par's own expense, it took less than a week to make the 1.5 million pages produced by plaintiffs text searchable.

Notwithstanding plaintiffs' decision to rely on attorney review to identify keywords (D.I. 177, De Decl., ¶ 21) and spot checking (D.I. 177, De Decl., ¶ 23), plaintiffs admit that even after recalling documents they did not re-review documents until before each deposition, when reviewing a particular name-set. (D.I. 177, De Decl., ¶ 28). *See Sherlock v. Lockheed Martin Corp.*, No. 01-254, 2002 U.S. Dist. LEXIS 27753, at *2, 6 (D. Md. Dec. 18, 2002) (ordering that the privilege has been waived on 10 inadvertently produced pages out of 4000 pages, i.e. 0.25% of the production, and holding that the opposing party "[has] a right to know if documents are not part of the litigation field of play."). The recalling of documents before nearly every deposition shows not only that reasonable precautions were not taken to avoid inadvertent production, but also that plaintiffs were unconcerned about whether other "inadvertently" produced documents could have been in Par's possession. (Ex. K). Accordingly, reasonable precautions were not taken before production, or after learning that allegedly privileged documents may have been produced. This factor weighs in favor of finding waiver.

b. The Number of Inadvertent Disclosures

The number of recalled documents is not in dispute. Plaintiffs have requested return of at least 1000 documents totaling approximately 65,000 pages. There has been no indication that plaintiffs have rectified the situation and will stop requesting return of "inadvertently" produced documents, either before the remaining depositions or at trial.

c. The Extent of the Disclosure

Plaintiffs rely on a miscalculation to justify their "inadvertent" document productions. According to plaintiffs, "The inadvertent disclosure totaled less than one half of one percent of

the more than 2.3 million pages produced.” (D.I. 176, Opposition Br., at 19). That is wrong. The extent of the disclosure of “inadvertently” produced documents is not “less than 0.3%” as plaintiffs have contended. (D.I. 176, Opposition Br., at 3, 12, 19; D.I. 177, De Decl., ¶ 27). Of the 2.3 million pages that plaintiffs and third parties produced, 65,000 pages were recalled. 65,000 pages out of 2.3 million pages is approximately 3%—not “less than 0.3%.” Plaintiffs’ calculation is an order of magnitude off:

$$\frac{65000}{2300000} = 0.0283 = 2.83\%$$

Approximately 3% of a 2.3 million page production is a substantial amount of documents to recall. See *Sherlock*, 2002 U.S. Dist. LEXIS 27753, at *2, 5 (ordering that the 10 “inadvertently” produced pages out of 4000 pages be produced, i.e. 0.25% of the production). This factor weighs heavily in favor of requiring production of the documents. See *Bensel*, 248 F.R.D. at 180 (finding that 155 pages of inadvertently produced documents out of a total production of 6000 pages, i.e. 2.58%, weighed in favor of waiver); compare *Ciba-Geigy Corp.*, 916 F. Supp. at 414 (finding that disclosure of seven documents totaling twenty-three pages out of 681 total documents weighed in favor of waiver), with *Maldonado v. New Jersey*, 225 F.R.D. 120, 129 (D.N.J. 2004) (finding that a “one-time leak situation” of one document weighed against waiver).

d. Delay In Rectifying the Inadvertent Disclosures

Plaintiffs represent that they “immediately withdrew documents upon learning of the disclosure.” (D.I. 176, Opposition Br., at 18). The record indicates, however, that plaintiffs took no steps to cure their initial review of the documents. Instead, plaintiffs leisurely recalled documents piece meal over the course of approximately five months with no sense of urgency, allowing Par’s attorneys to review and rely on these documents in preparation for depositions. To the prejudice of Par, the majority of these documents were recalled just prior to depositions of

Purdue's and Napp's witnesses. (Ex. K). In fact, plaintiffs claim that it would not have been "practical" to determine if other documents had been inadvertently produced. (D.I. 177, De Decl., ¶ 28). Instead of rectifying the situation, plaintiffs left the documents "in the litigation field of play" for several months. *See Sherlock*, 2002 U.S. Dist. LEXIS 27753 at *4. A similar situation occurred in *New Bank of New England v. Marine Midland Realty Credit Corp.*, 138 F.R.D. 479, 483 (E.D. Va. 1991), where the court held that after one privileged document was inadvertently produced, "a prudent party would have reviewed the documents produced once again to ensure that other privileged documents were not overlooked."

Given that one privileged document had been inadvertently disclosed, a prudent party would have reviewed the documents produced once again to ensure that other privileged documents were not overlooked. Rowe failed to take this step. Had it done so, it might well have discovered the other previously overlooked copies of the letter. In that event, it is unlikely that a waiver could be deemed to have occurred. In fact, however, Rowe's failure to conduct a check of the produced documents led to the inadvertent production of two more versions of the letter. Indeed, four days after the first disclosure, Rowe copied and delivered to NBNE the rough draft of the letter, which on its first page advertised prominently in underscored capital letters that it was a privileged communication. *Rowe's inadequate efforts to rectify the error of the inadvertent disclosure supports the conclusion of waiver.*

Id. (emphasis added).

It would have been reasonable for plaintiffs to simply prepare the documents in text-searchable format. Par accomplished the task of making the produced documents electronically searchable in less than a week. It is unclear why reviewing their production for privileged documents would have "stopped all other work on the lawsuit" and taken plaintiffs "weeks, if not months." (D.I. 176, Opposition Br., at 5, 14; D.I. 177, De Decl., ¶ 28). Accordingly, plaintiffs' deliberate decision to not adequately review documents based on workload concerns does not justify the failure to rectify the "inadvertent" disclosure situation. *See Sherlock*, 2002 U.S. Dist.

LEXIS 27753, at *4 (stating that “counsel’s explanation about the demands of the litigation schedule in this case are to no avail.”). This factor weighs heavily in favor of waiver.

e. Fairness

The overriding issue of fairness favors waiver because Par has relied on many of these documents in preparation for depositions and putting together its case, particularly its invalidity and unenforceability positions. Just as in *Bud Antle, Inc. v. Grow-Tech Inc.*, 131 F.R.D. 179, 184 (N.D. Cal. 1990) “the bell has already rung, and the court cannot now unring it by denying [defendant] access to the [documents].” Many of these documents have been in the litigation playing field for several months and plaintiffs have shown little concern for the allegedly privileged information until the night before or during depositions. The fairness factor also weighs heavily in favor of waiver.

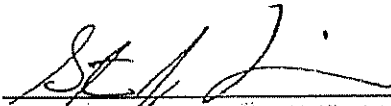
CONCLUSION

For the foregoing reasons, Par respectfully requests that the Court order the requested relief.

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**IN THE UNITED STATES DISTRICT COURT
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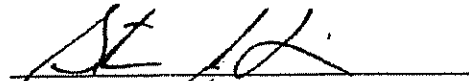
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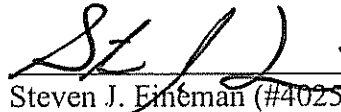
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